In re Application of: Elan ZIV Serial No.: 10/598,872 Filed: May 18, 2007

Office Action Mailing Date: February 14, 2011

Examiner: Catherine E. BURK

Group Art Unit: 3735 Attorney Docket: **34061** Confirmation No.: 1651

## **REMARKS**

The application contains claims 1-13, 15, 16, 18-22, 26-29, and 32-37. Claims 1, 6, 15, 18 and 26 are amended. Claim 14 has been previously canceled. Claims 23-25 and 30-31 have been withdrawn in response to the Restriction Requirement dated August 4, 2010. Claims 38 and 39 are new.

## Claim Rejections under 35 U.S.C. §102(b)

The Examiner has rejected claims 1-13, 15, 16, 20-22, 26-29, and 32-37 under 35 U.S.C. §102(b) in view of US 5,618,256 to Reimer. Applicant respectfully disagrees with this rejection for the reasons set forth below, namely that the examiner did not show a prima facie case of anticipation as the art does not show all the claim limitations of claim 1. Additional reasons will be detailed below.

Before referring to the rejection itself, applicants would like to note that the apparatus claimed, in some embodiments thereof, is suitable for providing urethral support which applies substantial force to the urethra only during episodes of intra-abdominal pressure increase, while Reimer's device operates by providing bladder neck support, whereby force is applied to the bladder neck at all times (Col. 2, line 47; Col. 5, line 60). This means that Reimer's device is generally designed to be inserted deeper, apply force against different parts of the body and use a greater force and apply it at all times. It is respectfully suggested that the use of greater force applied at all times (see vaginal indentation in Fig. 13 and Col. 4, line 60) allows Reimer to consider a device where all of the legs are on the same side of what the Examiner identifies as a node, with respect to the axis of the vagina.

In the rejection of claim 1, the Examiner indicates that the axis of the device could be perpendicular to the length of the device, and that Fig. 8 of Reimer is rotationally symmetric. Applicants respectfully disagree that that axis suggested by the examiner is a "central axis". Applicants also note that the device (and node) of Fig. 8 is mirror-symmetric. As the device of Fig. 8 is designed to be folded, it cannot be

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expected to have a rotational symmetry, especially not for its node. Nevertheless, applicant will make explicit what was previously implicit, namely, that the axis of symmetry is along the length of the device and along the vagina. Claim 26, the method claim, is amended in a similar manner. The issue of symmetry is emphasized in new claim 39.

Applicants also note that Reimer's device is not suitable for urethral support, at least because the forces applied would compress the urethra.

Referring now to at least some of the dependent claims:

Re claims 4 and 5. While col. 5 of Reimer does describe using additional legs, they are all on one side of the node (with respect to the central axis, vaginal axis). This is further emphasized in new claim 38.

Regarding claims 6 and 7, applicants respectfully disagree with the Examiner that a cover and a coating are the same thing. Nevertheless claim 6 is amended to clarify that the cover is a separate element.

Regarding claim 15, the claim has been amended to clarify that the length is in an uncompressed state.

Regarding claim 16. The ribs 27 are not extending inserts, but merely an integral portion which is not inserted and does not extend.

Regarding claim 33, it is noted that the "octopus" might be contemplated, but no useful embodiment of that number of legs is suggested, rather the word "like" is used.

Regarding claims 26, 35 and 37. Reimer, at Col. 2 and at Fig. 13 is clear that what is provided is bladder neck support (col. 3, line 5; col. 5, line 60), not urethral support. The forces required to maintain the device in place and shape (as shown in Fig. 13) are significant and can be expected to cause discomfort and blockage of urethra, if applied to urethra (which they are not). It is noted that various design elements are provided in Reimer to increase the force (e.g., bulges 25)

10

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Claim Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claims 18 and 19 over Reimer. Applicant

respectfully disagrees with this rejection for the reasons set forth below. As noted

above, Reimer's device operates by the device itself providing bladder neck support.

There is no suggestion that it might be desired to provide force using an intermediary

(the cover). There is also no suggestion that a separate cover might be desirable.

Applicant also repeats the observation that the force levels for urethral support are

generally considerably lower than used for bladder neck support and that they are not

applied to urethra at all times. The Examiner appears to interpret Reimer's device as

operating according to the principles described in the instant application and therefore

relevant to the claims. This is incorrect and also un-allowed hindsight.

It is believed that all issues have been dealt with and it is believed the

application is in condition for allowance. Prior to mailing of the Examiner's next

Official Action, if any, the Examiner and his Supervisor are invited to contact the

undersigned by telephone if it is felt that a telephone interview would advance the

prosecution of the present application.

Respectfully submitted,

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Enclosures:

Petition for Extension (1 Month)

• Request for Continued Examination (RCE)